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**ORTHOPAEDIC AND REHABILITATION DEVICES PANEL**  
**AGENDA****May 21, 2013****Orthopaedic Surgery and Rehabilitation Devices Panel**  
**515i Classification Panel**  
**Nonthermal Shortwave Diathermy Devices**  
**Gaithersburg Holiday Inn**

8:00 a.m.	Call to Order Introduction of Committee	<b>John D. Kelly IV, MD</b> Chairperson
	Conflict of Interest Statement	<b>Jamie Waterhouse</b> Designated Federal Officer
8:10 a.m.	Reclassification Presentation (10 min)	<b>Marjorie Shulman, M.B.A.</b> Director, Premarket Notification (510(k)) Program
8:20 a.m.	SWD Devices Regulatory History (20 min)	
8:40 a.m.	Question from Committee (15 min)	
8:55 a.m.	Industry Open Public Hearing (1.5 hr)	
10:25 a.m.	Questions from Committee (20 min)	
10:45 a.m.	Break (10 min)	
10:55 a.m.	FDA Presentation (1 hr)	
11:55 a.m.	Questions from Committee (20 min)	
12:15 p.m.	Lunch (1 hr)	
1:15 p.m.	Open Public Hearing (1 hr)	
2:15 p.m.	Panel Deliberations (1 hr)	
3:15 p.m.	Break (15 min)	
3:30 p.m.	FDA Questions to the Panel	
5:00 p.m.	Adjournment	

\* **Open Public Hearing** – Interested persons may present data, information, or views, orally or in writing, on the issue pending before the panel. Scheduled speakers who have requested time to address the panel will speak at this time. After they have spoken, the Chair may ask them to remain if the panel wishes to question them. Then the Chair will recognize unscheduled speakers as time allows. Only the panel may question speakers during the open public hearing.